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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/602,528	06/23/2000	Jan Eirik Ellingsen	06275-199001	9997

7590

10/09/2002

William E Booth  
Fish & Richardson P C  
225 Franklin Street  
Boston, MA 02110-2804

EXAMINER

CULBERT, ROBERTS P

ART UNIT	PAPER NUMBER
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1763

6

DATE MAILED: 10/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/602,528

Applicant(s)

ELLINGSEN ET AL.

Examiner

Roberts Culbert

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2002.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-78 is/are pending in the application.
- 4a) Of the above claim(s) 11-15 and 55-64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 16-54 and 65-78 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☒ Certified copies of the priority documents have been received in Application No. 08446675.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2. 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of claims 1-10, 16-54, and 65-78 in Paper No. 5 is acknowledged. The traversal is on the ground(s) that the implant of claims 11 and 12 can only be made by the method of claim 1. This is not found persuasive because a materially different process could form the implant of claims 11 and 12.

The requirement is still deemed proper and is therefore made FINAL.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-10, 16-40 and 65-78 are rejected under 35 U.S.C. 102(b) as being anticipated by Japanese Patent JP 3146679 to Haruyuki. Haruyuki teaches a method for treating the surface of a titanium biorepair implant and increasing the strength of the bond between bone tissue and the metallic implant. Haruyuki describes treatment of the titanium implant in a 1-6% solution of hydrofluoric acid for a time of 30 seconds to 3 minutes. It is assumed that that the hydrofluoric acid solution is free of sodium ions. It is assumed that the surface of the titanium implant is initially covered with a thin layer of titanium oxide because Haruyuki does not mention an oxygen-free environment. Although Haruyuki stresses the use of a post treatment

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with hydrogen peroxide, the use of hydrofluoric acid alone is clearly contemplated in Comparative Example 2. The results described in Table 1. indicate that post treatment is not needed to affect the surface properties. The purpose of the hydrogen peroxide post treatment is to reduce tissue irritation (Page 4 Line 30). Haruyuki teaches that only slight changes in morphology are needed to increase the attachment strength of the implant. Haruyuki indicates that features with an average depth below 0.5  $\mu\text{m}$  would have a small anchoring effect (Page 4 Lines 21-26).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haruyuki.

The above cited dependent claim differs from Haruyuki by specifying various compositions or process conditions. A person having ordinary skill in the art at the time of the claimed invention would have found it obvious to modify Haruyuki by using different processing parameters because same were known to be cause effective variables and routine experimentation would have been expected to optimize them. *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Changes in temperature, concentrations, or other process conditions of an old process, do not impart patentability unless the recited changes are critical, i.e., they produce a new and unexpected result. *In re Aller et al.*, 105 USPQ 233.

Claims 41-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haruyuki in view of the admitted prior art. As applied above, Haruyuki discloses the method of the invention substantially as claimed, but does not teach post treatment with a solution containing calcium ions. The admitted prior art (Page 7 Lines 10-15) describes post treatment with a solution of calcium ions. Therefore it would have been obvious to one of ordinary skill in the art at the time of invention to treat the implant with a solution containing calcium ions, in order to determine biocompatibility of the implant.

### *Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Riggs Jr., Steinemann, and Beaty show various methods for treating a titanium implant with hydrofluoric acid.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roberts Culbert whose telephone number is (703) 305-7965. The examiner can normally be reached on Monday-Friday (7:30-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory Mills can be reached on (703) 308-1633. The fax phone numbers for the

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organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

October 3, 2002

  
GREGORY MILLS  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1700